

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in this application:

Listing of Claims:

Claim 1 (Currently amended): A pharmaceutical preparation comprising:

- (a) an active substance comprising tiotropium or a pharmaceutically acceptable salt thereof, in a concentration based on tiotropium of between 0.0005 and 5% by weight;
- (b) a solvent selected from water or a water/ethanol mixture;
- (c) acid for achieving a pH between 2.0 and 3.0 ~~3.4~~; and
- (d) a pharmacologically acceptable preservative,

optionally including a pharmacologically acceptable complexing agent, a stabilizer, a pharmacologically acceptable cosolvent, or other pharmacologically acceptable adjuvants and additives.

Claim 2 (Previously presented): The pharmaceutical preparation according to claim 1, wherein the tiotropium salt is selected from the group consisting of bromide, chloride, iodide, monomethylsulphate, methanesulphonate and/or p-toluenesulphonate.

Claim 3 (Original): The pharmaceutical preparation according to claim 1, wherein the active substance is tiotropium bromide.

Claim 4 (Original): The pharmaceutical preparation according to claim 1, wherein the active substance is tiotropium bromide monohydrate.

Claim 5 (Original): The pharmaceutical preparation according to claim 1, wherein the solvent is water.

Claim 6 (Original): The pharmaceutical preparation according to claim 2, wherein the solvent is water.

Claim 7 (Original): The pharmaceutical preparation according to claim 3, wherein the solvent is water.

Claim 8 (Original): The pharmaceutical preparation according to claim 4, wherein the solvent is water.

Claim 9 (Original): The pharmaceutical preparation according to claim 1, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 10 (Original): The pharmaceutical preparation according to claim 2, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 11 (Original): The pharmaceutical preparation according to claim 3, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 12 (Original): The pharmaceutical preparation according to claim 4, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 13 (Original): The pharmaceutical preparation according to claim 9, wherein the solvent is a water-ethanol mixture with up to 60 vol.% of ethanol.

Claim 14 (Original): The pharmaceutical preparation according to claim 13, wherein the solvent is a water-ethanol mixture with up to 30 vol.% of ethanol.

Claim 15 (Previously presented): The pharmaceutical preparation according to claim 1, wherein the pharmaceutical preparation does not contain a complexing agent.

Claim 16 (Previously presented): The pharmaceutical preparation according to claim 1, wherein the pharmaceutical preparation does not contain a stabilizer.

Claim 17 (Previously presented): The pharmaceutical preparation according to claims 1, wherein the complexing agent comprises edetic acid salt in an amount of up to 25 mg/100 ml.

Claim 18 (Original): The pharmaceutical preparation according to claim 17, wherein edetic acid salt is present in an amount of from 5 to less than 10 mg/100 ml.

Claim 19 (Original): The pharmaceutical preparation according to claim 17, wherein the edetic acid salt is sodium edetate.

Claim 20 (Currently amended): The pharmaceutical preparation according to claim 1, wherein the pH is between 2.5 and 3.0 ~~3.4~~.

Claim 21 (Cancelled)

Claim 22 (Currently amended): The pharmaceutical preparation according to claim ~~24~~ 20, wherein the pH is between 2.7 and 3.0.

Claim 23 (Previously presented): The pharmaceutical preparation according to claims 1, wherein the concentration based on tiotropium is between 0.001% and 3% by weight.

Claim 24 (Original): The pharmaceutical preparation according to claim 23, wherein the concentration based on tiotropium is between 0.0005% to 0.5% by weight.

Claim 25 (Original): The pharmaceutical preparation according to claim 24, wherein the concentration based on tiotropium is between 0.0005% to 0.25% by weight.

Claim 26 (Original): The pharmaceutical preparation according to claim 25, wherein the concentration based on tiotropium is between 0.001% to 0.1% by weight.

Claim 27 (Previously presented): The pharmaceutical preparation according to claim 1, wherein the pharmacologically acceptable preservative is benzalkonium chloride.

Claim 28 (Previously presented): The pharmaceutical preparation according to claims 1, wherein the pharmaceutical preparation comprises a pharmacologically acceptable adjuvant or additive.

Claim 29 (Original): The pharmaceutical preparation according to claim 28, wherein pharmacologically acceptable adjuvant or additive is an antioxidant.

Claim 30 (Previously presented): The pharmaceutical preparation according to claims 1, wherein the pharmaceutical preparation contains no cosolvents and/or pharmacologically acceptable adjuvants and additives apart from the preservative.

Claim 31 (Original): A pharmaceutical preparation comprising water, 0.1% by weight of tiotropium bromide, 0.01% by weight of benzalkonium chloride, and 0.05% by weight of sodium edetate, which is adjusted to a pH of 3.0 using hydrochloric acid.

Claims 32-37 (Cancelled)

Claim 38 (Previously presented): A method for administering a pharmaceutical preparation according to claim 1, comprising nebulizing the pharmaceutical preparation in an inhaler selected from the group consisting of: (a) an inhaler according to the Weston Nebulizer, or (b) an inhaler according to the Jaeger Nebulizer B.

Claim 39 (Previously presented): A method for administering a pharmaceutical preparation according to claim 1, comprising nebulizing the pharmaceutical preparation in an inhaler which nebulizes defined amounts of the pharmaceutical preparation by the application of pressures from 100 to 600 bar through a nozzle having at least one nozzle opening with a depth of 2 to 10 microns and a width of 5 to 15 microns to form an inhalable aerosol.

Claim 40 (Original): The method according to claim 39, wherein at least one nozzle opening is at least two nozzle openings which are inclined relative to one another in the direction of the nozzle opening at an angle of from 20 degrees to 160 degrees.

Claim 41 (Original): The method according to claim 39, wherein the defined amounts of the pharmaceutical preparation are 10 to 50 microliters.

Claim 42 (Original): The method according to claim 38, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

Claim 43 (Original): The method according to claim 39, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

Claim 44 (Original): The method according to claim 38, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

Claim 45 (Original): The method according to claim 39, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

Claim 46 (Original): The method according to claim 38, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 47 (Original): The method according to claim 39, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 48 (Original): The method according to claim 38, wherein the mass of pharmaceutical formulation delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 49 (Original): The method according to claim 39, wherein the mass of pharmaceutical formulation delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 50 (Previously presented): A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation according to claim 1.

Claim 51 (Original): A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation using the method of claim 38.

Claim 52 (Original): A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation using the method of claim 39.

Claim 53 (Currently amended): A pharmaceutical preparation comprising:

- (a) an active ingredient consisting essentially of a tiotropium salt, in a concentration based on tiotropium of between 0.0005 and 5% by weight;
- (b) a solvent selected from water or a water/ethanol mixture;
- (c) acid for achieving a pH between 2.0 and 3.0 ~~3.4~~; and
- (d) a pharmacologically acceptable preservative,

optionally including a pharmacologically acceptable complexing agent, stabilizer, a pharmacologically acceptable cosolvent, or other pharmacologically acceptable adjuvants and additives.

Claim 54 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the tiotropium salt is selected from the group consisting bromide, chloride, iodide, monomethylsulphate, methanesulphonate and/or p-toluenesulphonate.

Claim 55 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the tiotropium salt is tiotropium bromide.

Claim 56 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the tiotropium salt is tiotropium bromide monohydrate.

Claim 57 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the solvent is water.

Claim 58 (Previously presented): The pharmaceutical preparation according to claim 54, wherein the solvent is water.

Claim 59 (Previously presented): The pharmaceutical preparation according to claim 55, wherein the solvent is water.

Claim 60 (Previously presented): The pharmaceutical preparation according to claim 56, wherein the solvent is water.

Claim 61 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 62 (Previously presented): The pharmaceutical preparation according to claim 54, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 63 (Previously presented): The pharmaceutical preparation according to claim 55, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 64 (Previously presented): The pharmaceutical preparation according to claim 56, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

Claim 65 (Previously presented): The pharmaceutical preparation according to claim 61, wherein the solvent is a water-ethanol mixture with up to 60 vol.% of ethanol.

Claim 66 (Previously presented): The pharmaceutical preparation according to claim 65, wherein the solvent is a water-ethanol mixture with up to 30 vol.% of ethanol.

Claim 67 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the pharmaceutical preparation does not contain a complexing agent.

Claim 68 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the pharmaceutical preparation does not contain a stabilizer.

Claim 69 (Previously presented): The pharmaceutical preparation according to claim 53, wherein edetic acid salt is present in an amount of up to 25 mg/100 ml.

Claim 70 (Previously presented): The pharmaceutical preparation according to claim 69, wherein the edetic acid salt is sodium edetate.

Claim 71 (Currently amended): The pharmaceutical preparation according to claim 53, wherein the pH is between 2.5 and 3.0 ~~3.4~~.

Claim 72 (Currently amended): The pharmaceutical preparation according to claim 71, wherein the pH is between 2.7 and 3.0 ~~3.4~~.

Claim 73 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the concentration based on tiotropium is between 0.001% and 3% by weight.

Claim 74 (Previously presented): The pharmaceutical preparation according to claim 73, wherein the concentration based on tiotropium is between 0.0005% to 0.5% by weight.

Claim 75 (Previously presented): The pharmaceutical preparation according to claim 74, wherein the concentration based on tiotropium is between 0.0005% to 0.25% by weight.

Claim 76 (Previously presented): The pharmaceutical preparation according to claim 75, wherein the concentration based on tiotropium is between 0.001% to 0.1% by weight.

Claim 77 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the pharmacologically acceptable preservative is benzalkonium chloride.

Claim 78 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the pharmaceutical preparation comprises a pharmacologically acceptable adjuvant or additive.

Claim 79 (Previously presented): The pharmaceutical preparation according to claim 78, wherein pharmacologically acceptable adjuvant or additive is an antioxidant.

Claim 80 (Previously presented): The pharmaceutical preparation according to claim 53, wherein the pharmaceutical preparation contains no cosolvents and/or pharmacologically acceptable adjuvants and additives apart from the preservative.

Claim 81 (Previously presented): A method for administering a pharmaceutical preparation according to claim 53, comprising nebulizing the pharmaceutical preparation in an inhaler selected from the group consisting of: (a) an inhaler according to the Weston Nebulizer, or (b) an inhaler according to the Jaeger Nebulizer B.

Claim 82 (Previously presented): A method for administering a pharmaceutical preparation according to claim 53, comprising nebulizing the pharmaceutical preparation in an inhaler which nebulizes defined amounts of the pharmaceutical preparation by the application of pressures from 100 to 600 bar through a nozzle having at least one nozzle opening with a depth of 2 to 10 microns and a width of 5 to 15 microns to form an inhalable aerosol.

Claim 83 (Previously presented): The method according to claim 82, wherein at least one nozzle opening is at least two nozzle openings which are inclined relative to one another in the direction of the nozzle opening at an angle of from 20 degrees to 160 degrees.

Claim 84 (Previously presented): The method according to claim 82, wherein the defined amounts of the pharmaceutical preparation are 10 to 50 microliters.

Claim 85 (Previously presented): The method according to claim 81, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

Claim 86 (Previously presented): The method according to claim 82, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

Claim 87 (Previously presented): The method according to claim 81, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

Claim 88 (Previously presented): The method according to claim 82, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

Claim 89 (Previously presented): The method according to claim 81, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 90 (Previously presented): The method according to claim 82, wherein the mass of pharmaceutical formulation delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 91 (Previously presented): The method according to claim 81, wherein the mass of pharmaceutical formulation delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 92 (Previously presented): The method according to claim 82, wherein the mass of pharmaceutical formulation delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

Claim 93 (Previously presented): A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation according to claim 53.

Claim 94 (Previously presented): A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation using the method of claim 81.

Claim 95 (Previously presented): A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical preparation using the method of claim 82.